

**Advisory Action
Before the Filing of an Appeal Brief**

Application No. 09/926,661	Applicant(s) CHIBA, MASATOSHI
Examiner DANIEL KOLKER	Art Unit 1649

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 03 November 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on 09 November 2009. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: 1, 3, 4 and 6-16.
Claim(s) withdrawn from consideration: 22-28.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Daniel E. Kolker/
Primary Examiner, Art Unit 1649
November 18, 2009

Continuation of 11, does NOT place the application in condition for allowance because: The remarks and arguments filed 11/3/09 have been fully considered but they are not persuasive. The examiner acknowledges that applicant points to evidence in the specification that indicate how the invention as claimed is different from that of Tanaka. However, given the teachings of both Tanaka and Yamahira, the results obtained are not at all unexpected. Tanaka explicitly teaches lyophilized compositions comprising HGF a stabilizer, NaCl, buffer, and a surface active agent (see paragraph [0008] for example). Tanaka also teaches that amino acids in general are suitable stabilizers. Yamahira teaches that several amino acids, including arginine, lysine, and histidine (among others) act to stabilize a lyophilized composition. Thus combining the teachings would have been obvious, since Tanaka teaches that amino acid stabilizers should be used, and Yamahira teaches several of the particular amino acids recited as stabilizers in the present claims. Furthermore, the references by Bernardi and by Gits, cited at the bottom of p. 5 of the office action mailed 8 May 2009, provide a reasonable expectation of success in using arginine to increase stability of lyophilized compositions. Thus the fact that applicant found that stability of lyophilized HGF could be enhanced, or aggregates could be decreased, by addition of arginine or certain other recited amino acids, is not at all unexpected or surprising, but is what one of ordinary skill in the art would have expected, given that these amino acids were well-known to be stabilizers in lyophilized compositions. Additionally, to the extent that the recited concentration of the starting material is different from that used by Tanaka, such differences do not constitute a patentable contribution, since modifying concentration would be a parameter that one of ordinary skill in the art would optimize. Therefore, the rejection under 35 USC 103(a) stands.